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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,883	11/21/2000	Susana Salceda	DEX-0115	2018

26259 7590 07/30/2004

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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 07/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/717,883	SALCEDA ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 3 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/09/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response, CRF, and a new Sequence Listing filed on 05/19/2004 are acknowledged.

Specification

The amendment filed 5/13/2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: SEQ ID NO:5 in the new Sequence Listing filed on 5/13/2004 is new matter because the instant application as originally filed does not have support for SEQ ID NO:5 since the Provisional Application 60/166,818 is not incorporated by reference.

Applicant states that SEQ ID NO:5 is same as SEQ ID NO:1 in the Provisional Application 60/166,818 that the instant application claims priority benefit. However, anything the disclosed in the instant application and also disclosed in the Provisional Application 60/166,818 is entitled to priority benefit to the filing date of the Provisional Application. However, something not disclosed in the instant application as originally filed cannot be added based on priority to earlier Provisional Application.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112, Maintained

Claim 3 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites "under stringent conditions" but it is not clear what the metes and bounds are. The specification does not define the stringent conditions.

Applicant argues that methods for assessing whether a polynucleotide hybridizes under stringent conditions to a selected polynucleotide sequence are well known to those of skill in the art and set forth in great detail in standard reference texts such as Sambrook et al. 1989 (Molecular Cloning, A Laboratory Manual, 2nd Edition, Cold Spring Harbor Press, Cold Spring Harbor). Such methods can be performed routinely by those of skill in the art to assess whether or not a polynucleotide hybridizes under stringent conditions to, for example SEQ ID NO:1 and thus falls within the scope of the claimed polynucleotides. These argument have been fully considered but found unpersuasive because what is "stringent conditions" are subject to interpretation by different individual, thus it is not clear the definite boundaries on the patent protection sought.

Claim 3 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On close

re-examination of claim 3 along with the specification at page 6 lines 13-21, the Office interprets that the claim is not limited SEQ ID NO:1. This rejection is based on the limitation "Ovr107 comprises...a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:1". There is a lack of written description for Ovr107 comprise a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:1. The claims are interpreted as drawn to cancer diagnosis method by detecting **a genus of nucleotides molecules** that are defined only by hybridization under stringent condition.

Applicant states that the claim is amended to include SEQ ID NO:5 but this argument is drawn to a limitation not present in the claim.

Claim 3 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection in cells and tissue sample, does not reasonably provide enablement for **bodily fluids**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

This rejection is based on the interpretation of the claim is drawn to method of diagnosing cancer by detecting increased level of SEQ ID NO:1 in **bodily fluids** from a patient.

Applicant argues that a quick search of the relevant art revealed multiple prior art and contemporary references disclosing detection of cancer markers in various bodily fluids. Applicant argues that the attached abstracts are clearly

supportive of polynucleotides such as SEQ ID NO:I being detectable in bodily fluids. Further, MPEP 5 2164.01 states that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claimed invention, then the enablement requirement of 35 U.S.C. 5 112, is satisfied. Those of skill in the art use exemplary bodily fluids routinely.

These arguments have been fully considered but found unpersuasive because the attached abstracts are about detection of nucleic acid in cancer cells being circulated.

The specification at Table 2 (page 21-30 discloses higher expression of SEQ ID NO:1 in tissues from ovarian, lung, endometrium cancer and also how to detect such expression using the disclosed probes at page 20 lines 15-17. However, the specification does not teach whether the nucleic acid molecule is also detected in bodily fluids. The specification does not teach increased expression of SEQ ID NO:1 in circulated cancer cells. The specification is silent about expression of SEQ ID NO:1 in circulated cancer cells. All of the attached abstract rather support the Office position i.e. it would require undue experimentation screening a large number of clinical samples to determine whether circulated cancer cells over-express SEQ ID NO:1.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

LARRY R. HELMS, PH.D
PRIMARY EXAMINER